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Editors: Leslie Demaree Goldsmith and Carel T. Hedlund

CMS Proposes Rule on Signature on Laboratory Requisitions – A Trip Back to the Future

By: Robert E. Mazer

In a previous *Payment Matters* article, we reported that CMS had instructed its Medicare contractors not to enforce the requirement that it had included in the Medicare Physician Fee Schedule Rule (MPFS) for calendar year 2011, requiring a physician or qualified non-physician practitioner (NPP) to sign the requisition for a clinical diagnostic laboratory test. "CMS Sign-Off - No Enforcement of Physician Signature Requirement on Lab Requisitions" (April 28, 2011). We indicated that rescission of the requirement might, however, require the agency to comply with Administrative Procedure Act (APA) notice and comment requirements. That has turned out to be the case.

On June 30, 2011, CMS issued a proposed rule that would retract the signature requirement [PDF]. CMS explained its policy change by stating that there were many situations, including frequent delay of care, that it could not have recognized as being problematic until it finalized the policy and received comments from "industry stakeholders" who had begun to implement it.

The agency, however, does not appear willing to abandon totally the physician signature requirement. CMS states in the proposed rule: "The requirement that the treating physician or NPP must document the ordering of the test remains, as does our longstanding policy that requires orders, including those for clinical diagnostic laboratory tests, to be signed by the ordering physician or NPP." CMS, therefore, proposes effectively to return to the policy that was part of the 2010 MPFS, requiring a signed physician order, such as a signed entry in the patient's medical record. This policy was met with great resistance by representatives of the laboratory industry who were able to demonstrate that the policy reflected a significant departure from longstanding agency policy, as reflected in CMS manuals.

Ober|Kaler's Comments

In some respects, the proposed policy may place laboratories in a more difficult position than they would have been if CMS had continued its policy requiring a signed laboratory requisition. Under that now-abandoned policy, a laboratory could determine if the physician signature requirement was satisfied by reviewing the requisition. If the proposed policy is adopted, without change, then in the absence of a signed requisition (which would appear to satisfy CMS requirements), a laboratory will be required to assume that the test order included within the medical record maintained by the physician was signed. In such an event, the lab must also hope that the physician will provide a copy of that record to the laboratory or Medicare contractor, should a particular claim be called into question.

CMS is required under the APA to consider comments addressing this proposed policy. These comments could seek clarification of the application of the policy (for example, that a signed requisition is adequate) or urge the agency to revise the policies reflected in the proposed rule. These comments could raise practical concerns, particularly if they adversely affect care to Medicare Program beneficiaries. Alternatively, they could raise legal or regulatory issues, such as the application of Medicare statutory limitation of liability provisions that protect laboratories from liability where they would have no reason to know that certain Medicare coverage requirements were not satisfied. Comments are required to be filed **on or before August 29, 2011**.